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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,888	12/01/2004	John W. Erickson	38911-0006US1	8886

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EXAMINER

BARKER, MICHAEL P

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 10/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/500,888	Applicant(s) ERICKSON ET AL.	
	Examiner Michael P. Barker	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/2/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-32 are pending in this Application.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on, August 2, 2005 was correctly filed. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement was considered by the Examiner.

Election/Restriction

Applicant's election without traverse of Group I(b) in the reply filed on July 5, 2006 is acknowledged. The restriction is final and the nonelected subject matter is withdrawn from further consideration. Please amend the Claims accordingly. Group I(b) is not free of prior art necessitating the rejections which follow.

Claim Rejections - 35 USC § 102(b)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 7, 10, 11, and 16-32 are rejected under 35 U.S.C. 102(b) as being anticipated by WIPO Publication No. WO 00/76961 A1, published December 21, 2000. The '961 publication discloses compounds and pharmaceutical compositions well suited for inhibiting

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HIV-1 and HIV-2 protease activity. Example 26 at p. 34 anticipates Applicant's broad Markush language of **Claim 1**, wherein **X** is a 5-7 membered non-aromatic monocyclic heterocycle, **A** is **ZCZNH** and **Z** is O, **B** is as defined wherein **D** is alkyl optionally substituted with **R6** wherein **R6** is aryl optionally substituted with **OR2** wherein **R2** is C1 alkyl substituted by aryl.

Considering the magnitude of the Markush language of **Claim 1**, it is impossible to point out each and every anticipating structure within the '961 publication. However, a few more structures which anticipate **Claim 1** include: Example 31, p. 34; Example 33, p. 35; Example 36, p. 35; Example 37, p. 35; Example 38, p. 35, etc. Please refer to the copy of the '961 publication submitted herewith.

Claim Rejections - 35 USC § 102(e)

The following are quotations of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 15, and 16-32 are rejected under 35 U.S.C. 102 (e) as being anticipated by US Publication No. 2004132791 A1, published July 8, 2004, claiming priority to Provisional Application No. 60/287,704, filed May 2, 2001. The '791 publication discloses compounds and pharmaceutical compositions and their use as broadspectrum HIV protease inhibitors. Example 2 at p. 21 anticipates Applicant's broad Markush language of **Claim 1**. Every anticipating

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structure will not be listed. A few more structures anticipating **Claim 1** include: Examples 3, 5, 6, and 9, p. 21. Please refer to the copy of the '791 publication submitted herewith.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is uncertain from the language of **Claim 24** as to what compounds Applicant is claiming. While the language of **Claim 1** clearly identifies the genus of compounds on which Applicant intends to acquire patent protection, the language of **Claim 24** does not clearly and specifically draw definite boundaries as to what is regarded as Applicant's invention.

Secondly, **Claim 24** recites the limitation "designated in Table 8". There is insufficient antecedent basis for this limitation in the claim. This rejection can be overcome by incorporating Table 8 into the claims or by omitting the reference to Table 8.

Double Patenting - Obviousness Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

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F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. **Claims 1, 2, 7, 8, 11, and 16-30** are rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over:

Claims 20-28 of allowed Application No. 10/606,342 (Notice of Allowance issued on 10 July 2006).

2. Likewise, **Claims 1, 2, 7, 8, 11, and 16-30** are provisionally rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over:

Claims 1-3 and 6-35 of copending Application No. 11/077,135; and

Claims 1-29 of copending Application Nos. 11/124,056 and 11/490,261.

This latter rejection is a *provisional* double patenting rejection since the conflicting claims have not yet been patented.

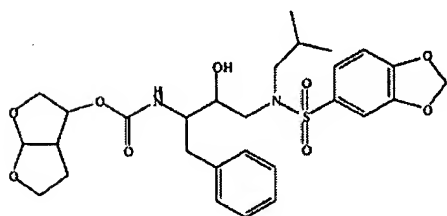
Applicants instant elected invention discloses the compounds and compositions of the formula, **X-A-B-A'-X'**, depicted in **Claim 1**. **Claims 2-32** narrow the scope of **Claim 1**'s broad

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Markush language and describe pharmaceutical compositions based on **Claim 1** and a method of treatment using those compositions.

Determination of the Scope and Content of the Allowed and Copending Applications

Claims 20-28 of allowed Application No. 10/606,342 discloses the composition,



Claims 1-3 and **6-35** of copending Application No. 11/077,135 and **Claims 1-29** of copending Application Nos. 11/124,056 and 11/490,261 each disclose compositions similar to the compound depicted above.

Ascertainment of the difference between the prior art and the claims (MPEP § 2141.02)

ODP Rejection: The differences between the instant Application and allowed Application No. 10/606,342 are slight. **Claims 20-28** of allowed Application No. 10/606,342 are drawn to drawn to pharmaceutical compositions encompassed by the Markush language of the instant Application's Claim 1. The difference lies in the fact the instant Application is drawn to a broad genus of compounds encompassing the species disclosed in allowed Application No. 10/606,342. Thus, considering the suggestion for narrowing the broad genus of **Claim 1** found in **Claims 7** and **11**, one of ordinary skill in the art would be motivated to produce the species common to the applications. The motivation to make the instantly claimed compounds derives from the expectation that structurally similar compounds would also possess similar activity.

Provisional ODP Rejection: The same reasoning can be extrapolated to provisionally reject **Claims 1, 2, 7, 8, 11, and 16-30** based on copending Application Nos. 11/077,135 (**Claims 1-3 and 6-35**); and copending Application Nos. 11/124,056 and 11/490,261 (**Claims 1-29**). Each of the aforementioned copending Applications claim pharmaceutical formulations containing overlapping pharmaceutical compositions as the instant Application.

Finding of prima facie obviousness - rationale and motivation (MPEP § 2142-2413)

One skilled in the art would have found the claimed compounds prima facie obvious over the copending applications because the instantly claimed compounds fall within the claims of the copending applications and the preferred species for the variables are the same and claimed in all the applications. Furthermore, the copending Applications teach one of ordinary skill in the art how to create the compounds claimed in the instant application. Given the preferred embodiments and the specific embodiments listed in the claims, one of ordinary skill in the art would be motivated to produce the species common to the applications. The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (i.e. pharmacological use). Both the instantly claimed compounds and the compounds of the copending applications are used for producing an antibacterial effect in a warm blooded animal. Although, the conflicting claims are not precisely identical, they are not patentably distinct from each other because applicant's instantly claimed invention is disclosed in the copending applications. Therefore, one skilled in the art would have found the slight variation obvious when faced with the copending applications because the compounds are used

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for the same pharmacological use so one skilled in the art would expect similar properties and results.

According to MPEP 804 I (B)(1), if a provisional obviousness type double patenting rejection is the only outstanding rejection, it may be issued in a junior case, where other terminal disclaimers have been filed in copending applications. MPEP 804 I (B)(1) states:

1. Nonstatutory Double Patenting Rejections

If a “provisional” nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications, while the later-filed application is rejectable on other grounds, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer. If the ODP rejection is the only rejection remaining in the later-filed application, while the earlier-filed application is rejectable on other grounds, a terminal disclaimer must be required in the later-filed application before the rejection can be withdrawn.

If “provisional” ODP rejections in two applications are the only rejections remaining in those applications, the examiner should withdraw the ODP rejection in the earlier filed application thereby permitting that application to issue without need of a terminal disclaimer. A terminal disclaimer must be required in the later-filed application before the ODP rejection can be withdrawn and the application permitted to issue. If both applications are filed on the same day, the examiner should determine which application claims the base invention and which application claims the improvement (added limitations). The ODP rejection in the base application can be withdrawn without a terminal disclaimer, while the ODP rejection in the improvement application cannot be withdrawn without a terminal disclaimer.

Where there are three applications containing claims that conflict such that an ODP rejection is made in each application based upon the other two, it is not sufficient to file a terminal disclaimer in only one of the applications addressing the other two applications. Rather, an appropriate terminal disclaimer must be filed in at least two of the applications to link all three together. This is because a terminal disclaimer filed to obviate a double patenting rejection is effective only with respect to the application in which the terminal disclaimer is filed; it is not effective to link the other two applications to each other.

Double Patenting – Statutory

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-32 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of **Claims 1-32** of copending Application Nos. 11/490,111 and 11/490,155.

This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Conclusion

Claims 1, 2, 7, 10, 11, and 16-32 are rejected under 35 U.S.C. 102(b) as being anticipated by WIPO Publication No. WO 00/76961 A1, published December 21, 2000. **Claims 1, 15, and 16-32** are rejected under 35 U.S.C. 102 (e) as being anticipated by US Publication No. 2004132791 A1, published July 8, 2004, claiming priority to Provisional Application No. 60/287,704, filed May 2, 2001. **Claims 1, 2, 7, 8, 11, and 16-30** are rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over **Claims 20-28** of allowed Application No. 10/606,342 (Notice of Allowance issued on 10 July 2006). **Claims 1, 2, 7, 8, 11, and 16-30** are provisionally rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over **Claims 1-3 and 6-35** of copending Application No. 11/077,135; and **Claims 1-29** of copending Application Nos. 11/124,056 and 11/490,261. **Claims 1-32** are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of **Claims 1-32** of copending Application Nos. 11/490,111 and 11/490,155.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael P. Barker whose telephone number is (571) 272-4341. The examiner can normally be reached on Monday-Friday 8:00 AM- 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699. The unofficial fax phone for this group are (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is viable through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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